

FACTSHEET
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P.O. Box 12233
MD: A3-01
Research Triangle Park
N.C. 27709-2233

headquartered at the

NATIONAL
INSTITUTE OF
ENVIRONMENTAL
HEALTH SCIENCES

NATIONAL
INSTITUTES
OF HEALTH

for further information
contact the NTP Liaison
Office at:
919-541-0530
Fax: 919-541-0295
liaison@starbase.niehs.nih.gov

The 9th Report on Carcinogens' (RoC) Listing of Tamoxifen as a known Human Carcinogen

Today the Department of Health and Human Services released the 9th edition of the RoC. The RoC, prepared by the National Toxicology Program (NTP), identifies substances -- such as metals, pesticides, drugs, and natural and synthetic chemicals -- that are "*known*" or are "*reasonably anticipated*" to cause cancer, and to which a significant number of Americans are exposed. The *Report* is a scientific and public health document first ordered by Congress in 1978 because many cancers appear to be caused by exposure to substances in the environment including the home and workplace, or from use of agents such as food additives, pesticides or pharmaceuticals.

Tamoxifen has been added to the 9th edition of this *Report*. It is listed as "*known to be a human carcinogen*" based on sufficient evidence of carcinogenicity from studies in humans that indicate a causal relationship between exposure to tamoxifen and cancers of the uterine endometrium. While there is clear evidence that tamoxifen increases the risk of uterine cancer in women taking the drug, there is also conclusive evidence that tamoxifen therapy is effective in the treatment of breast cancer, reduces the risk of recurrence of breast cancer when administered after breast cancer surgery, reduces the risk of contralateral breast cancer in women with a previous diagnosis of breast cancer, and reduces the incidence of breast cancer in women at high risk of this diagnosis. Tamoxifen is approved by the Food and Drug Administration (FDA) for all four indications.

The classification of tamoxifen in the *Report* as a "*known human carcinogen*" is consistent with a 1996 review by the International Agency for Research on Cancer which, using similar data, also classified tamoxifen as a "*known human carcinogen*."

The RoC is based on expert, scientific judgment, with consideration of all relevant information. The *Report* only identifies cancer health hazards. It is not within the scope of the *Report* to address potential benefits of certain carcinogenic substances in special situations. For example, numerous drugs used to treat cancer have been shown to increase the frequency of secondary cancers. For these FDA approved pharmaceuticals, the benefits of exposure to the drug outweigh the risks. Personal decisions concerning voluntary exposures to

carcinogenic agents need to be based on information that is beyond the scope of the *Report*.

In the case of tamoxifen, the FDA has approved its use to reduce the incidence of breast cancer in women determined to be at high risk of getting breast cancer, based on its analysis that the benefits of its use outweigh the additional cancer risks. Women should not make decisions about the therapeutic use of tamoxifen based on the information contained in this *Report*. Decisions of this type should be made after consulting with a physician or other appropriate specialist. It is very important that the public and physicians be given accurate information on potential risk so they have the information to weigh the benefits versus the risks of using tamoxifen.

Questions regarding the 9th RoC should be directed to the NTP Liaison and Scientific Review Office at telephone (919) 541-0530, fax (919) 541-0295, e-mail ntp@niehs.nih.gov

Women seeking additional information on the risks and benefits of using tamoxifen may contact the National Cancer Institute's Cancer Information Service at <http://cis.nci.nih.gov> or call toll free 1-800-4-CANCER (1-800-422-6237); TTY (for deaf and hard of hearing callers) 1-800-332-8615.

The 9th edition of the RoC is available on the NTP RoC Homepage <http://ntp-server.niehs.nih.gov/NewHomeRoC/AboutRoC.html> or by contacting the NTP-RoC, MD EC-14, P.O. Box 12233, Research Triangle Park, NC 27709. Phone (919) 541-4096; e-mail jameson@niehs.nih.gov

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